CLAIMS

sub A1

1. A process of analyzing a specimen of biological material in a biochemical or immunological test for an analyte, comprising the steps of:

subjecting the specimen to treatment which develops a color correlating to the amount of analyte in the specimen;

measuring at least one defined color characteristic, selected from hue angle, chroma, saturation and lightness of the developed color; and

analyzing the measurement of said at least one color characteristic to determine the presence or concentration of said analyte in the specimen.

2. A process according to claim 1, wherein said specimen of biological material comprises liquid and semi-solid body secretions collected from a patient to be diagnosed for evidence of abnormalities,

said analyte consists essentially of cancer indicating markers in the specimen, and

the measurement of said at least one color characteristic is used to classify the specimen as normal or abnormal according to the value of the color characteristic so obtained.

3. The process of claim 2, wherein the sample is lung mucus, throat mucus, cervical mucus or seminal fluid.

4. The process of claim 2 or claim 3, wherein the sample collected from a human patient is deposited on a generally white substrate, and the process includes developing color from said sample by enzyme reaction, determining at least one defined color characteristic selected from hue angle, chroma or saturation, and lightness, of the color so developed, and classifying the sample as normal or abnormal according to the defined characteristic of the color so developed.

5. The process according to claim 1, wherein said specimen of biological material comprises colon-contacting semi-solid samples collected from a patient to be diagnosed for evidence of abnormalities

said analyte consists essentially of carbohydrate markers indicative of abnormalities,

the step of subjecting the specimen to treatment comprises depositing the specimen on a generally white substrate, staining the sample on the substrate with galactose oxidase and color developing the stained sample with Shifts reagent, and

the measurement of said at least one color characteristic is used to classify the specimen as normal or abnormal according to the value of the color characteristics so obtained.

6. The process of analyzing a specimen of biological material according to claim 1, wherein said specimen of biological material comprises a colon-contacting semi-solid sample collected from a patient to be diagnosed for evidence of abnormalities,

said analyte consists essentially of markers indicative of the presence of abnormalities,

the step of subjecting the specimen to treatment comprises depositing the specimen on a generally white substrate and developing color from the specimen by enzyme reaction; and

the measurement of said at least one defined color characteristic is used to classify the sample as normal or abnormal according to the defined characteristic of the color so developed.

7. The process of any previous claim, wherein the defined color characteristic is the hue angle, and the hue angle is determined spectrophotometrically.

8. The process of any one of claims 2 to 6, wherein the substrate is non-cellulosic.

9. The process of any one of claims 2 to 6, wherein the substrate is glass fibre.

10. The process of any one of claims 2 to 6, wherein the substrate is substantially pure white.

11. The process of any one of claims 5 to 10, wherein the sample is predominantly a rectal mucus sample.

Sub A1

12. A system for analysis of liquid or semi-solid body secretion samples obtained from human patients to diagnose for the presence or absence of abnormalities in the patient, by utilization of determination of a defined color characteristic developed in the sample and selected from hue angle, chroma or saturation, and lightness, said system comprising: a white, non-cellulosic substrate with a porous "pebbled" surface, for receiving and holding the sample during development;

a source of galactose oxidase, adapted to apply galactose oxidase to the substrate surface for selective enzymatic oxidation of the sample thereon;

a source of Schiff's Reagent, adapted to apply Schiff's Reagent to the oxidized sample on the substrate for development of analyzable therein.

and means for presenting the color-developed sample to a portable reflectance spectrophotometer capable of determining and reporting a defined color characteristic selected from hue angle, chroma or saturation, and lightness from stained samples on said substrate.

13. A kit for analysis of colon-contacting semi-solid samples obtained from human patients to diagnose for the presence or absence of rectal abnormalities in the patient, comprising;

a generally white, non-cellulosic substrate for receiving the sample;

a source of Schiff's Reagent; and

a portable reflectance spectrophotometer capable of determining and reporting at least one defined color characteristic selected from hue angle, chroma or saturation, and lightness, from stained samples on said substrate.

14. A kit according to claim 8 wherein the substrate is glass fibre.

Sub A1

15. A process according to claim 1, wherein said specimen of biological material is the skin surface of a patient and said analyte is skin cholesterol.

16. A process of determining skin cholesterol levels of a patient, comprising:

applying to the patient's skin surface a reagent which selectively binds to skin cholesterol;

causing a color developing chemical reaction with the skin cholesterol-boundary reagent so formed, to form a color complex; and

subjecting the color complex so formed to spectrophotometric analysis to read therefrom a pre-defined characteristic of the colored complex selected from hue angle, chroma, saturation and lightness.

17. A process according to claim 16, wherein said reagent which selectively binds to skin cholesterol is selected from the group consisting of

(i) steroid glycosides, containing as an aglycone a cyclopentaneperhydrophenanthrene fragment of the furostanole or spirostanole series, and an oligosaccharide fragment including 3 to 10 monosaccharide residues with linear or branched structures,

(ii) triterpene glycosides, containing an aglycone of alpha or beta-amyryl, lupane, hopane, dommarane, linostane or holostane series, and oligosaccharides comprising saccharide residues of branched or linear structure,

(iii) hydrophobic proteins capable of discriminately forming a complex compound with cholesterol,

(iv) protein toxins, capable of discriminately forming complex compounds with cholesterol,

(v) polyens antibiotics, capable of discriminately forming complex compounds with cholesterol, and

(vi) high affinity enzymes, whose substrate is cholesterol, and which have a high affinity to it,

and formation of said colored complex is brought about by treatment of said binding agent on the skin surface first with a visualizing agent and then with an indicating agent.

18. A process according to claim 17, wherein formation of said color complex is brought about by treatment of said cholesterol binding agent on the skin surface successively with a bridging agent, a visualizing agent and an indicating agent.

19. A process according to claim 17 or claim 18, wherein said cholesterol binding agent is digitonin.

20. A process according to any one of claims 17 to 19, wherein said visualizing agent is peroxidase enzyme and said indicator agent contains hydrogen peroxide, N,N-diethel-p-phenylidene sulfate, together with appropriate stabilizers.

21. A kit for determination of skin cholesterol levels of a human patient, comprising:

a source of detecting agent, capable of binding to skin cholesterol of the patient to form a bound combination therewith on the skin;

a source of visualizing agent, capable of binding with the detecting agent-binding agent bound combination to form an optically altered complex;

a source of developing agent and means for applying the developing agent to the optically altered complex, to develop color therein; and

means for confining and for presenting said optically altered complex to a portable reflects spectrophotometer to determine therefrom a defined color characteristic selected from hue angle, chroma or saturation.

22. A kit according to claim 21, wherein said means for confining and presenting the optically altered complex to the spectrophotometer comprises a container in the form of a skin-adherent strip having at least one well passing therethrough for containment of the reagents in said well in contact against the skin of the patient.